



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,108	06/26/2006	Bo Rud Nielsen	P70653USD	1450
136 7590 10/27/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER HEYER, DENNIS				
ART UNIT		PAPER NUMBER		
1628				
MAIL DATE		DELIVERY MODE		
10/27/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/540,108

Applicant(s)

NIELSEN ET AL.

Examiner

DENNIS HEYER

Art Unit

1628

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 13, 2009 has been entered.

Acknowledgement is made of Applicant's remarks and amendments filed October 2, 2009. Acknowledgement is made of the amendment to independent Claims 11 and 20 which now include the limitation 'wherein said curing is the only irradiation step in the process'.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 11 – 21 are currently pending

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11 – 13 and 15 – 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in US 2002/0037943 (published: March 28, 2002) in view of Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003).

Madsen teaches a method for sterilizing a medical device comprising a hydrophilic coating (Abstract). With respect to claims 11, 17, 19 and 20, Madsen discloses in Examples 2 and 3, a method for the preparation of a cross-linked

hydrophilic coating of a hydrophilic polymer on a substrate polymer surface of a medical device (catheter), said method comprising the steps of (i) providing a medical device comprising a substrate polymer having the substrate polymer surface, (ii) providing a polymer solution comprising 1 – 20% by weight of a hydrophilic polymer and 0 – 5% by weight of additive(s), (iii) applying said polymer solution to said substrate polymer surface, (iv) evaporating at least a part of the vehicle from said polymer solution present on said substrate polymer surface, and curing said hydrophilic polymer (Example 1). Amended Claims 11 and 20 now recite the limitation 'wherein said curing is the only irradiation step in the process'. With respect to this limitation, Madsen teaches a final step, a sterilization step, in which a catheter (a medical device) is permanently wetted (coated) by the wetting liquid and thus ready to use and which may be sterilized by irradiation or autoclaving (emphasis added by Examiner) and which will retain the water retention and thus low coefficient of friction when the coatings are stored in water for an extended period of time" (paragraph [0039]). Since sterilization by autoclaving is not an irradiation step, Madsen clearly teaches the limitation of amended Claims 11 and 20, in which coated medical devices are prepared by the instantly claimed method steps.

Madsen further discloses providing a plasticizer (paragraph [0070]), however fails to expressly disclose the polymer solution comprises a vehicle with plasticizing effect on the hydrophilic polymer, said vehicle comprising at least one plasticizer having a solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20. Hunter *et al.* teach compositions and methods for coating medical implants (Title) and further teaches polymer coatings comprising triethyl

citrate as a plasticizer in order to increase the flexibility of the coating (paragraphs [0095], [0109]). Since Applicant's example includes the same plasticizer, the Examiner interprets the triethyl citrate has the same properties as claimed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the type of plasticizer taught by Hunter in the method of Madsen with a plasticizer recognized in the art to increase flexibility in order to attain a coating with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

With respect to claim 12, the modified Madsen discloses the polymer solution is applied to said substrate polymer surface in one single application step (dipping) (Examples 2 and 3).

With respect to claim 13, the modified Madsen discloses the vehicle comprises at least one solvent (ethanol) (Examples 2 and 3).

With respect to claim 15, the modified Madsen discloses the substrate polymer is polyurethane (Example 2).

With respect to claims 16 and 21, the modified Madsen discloses the hydrophilic polymer is polyvinyl pyrrolidone (Examples 2 and 3).

With respect to claim 18 Madsen discloses a medical device comprising a hydrophilic coating of a cross-linked hydrophilic polymer, wherein the coating comprises a plasticizer (paragraph [0070]) but fails to expressly disclose the plasticizer has a

solubility in water of at least 6 g/L, a boiling point above 210°C at 760 mmHg, and a Hansen δ_H parameter of less than 20.

Hunter *et al.* teach compositions and methods for coating medical implants (Title) and further teaches polymer coatings comprising triethyl citrate as a plasticizer in order to increase the flexibility of the coated device (paragraphs [0095], [0109]). Since Applicant's example includes the same plasticizer, the Examiner interprets the triethyl citrate has the same properties as claimed. Therefore, it would have been obvious to one of ordinary skill in the art to modify the type of plasticizer taught by Hunter in the method of Madsen with a plasticizer recognized in the art to increase flexibility in order to attain a coated device with the desired properties (desired flexibility). Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Madsen in US 2002/0037943 (published: March 28, 2002) and Hunter *et al.* in US 2004/0043052 (filed: May 27, 2003), as applied to Claims 11 – 13 above, and further in view of Larsen *et al.* in US patent 5,484,565 (published January 16, 1996).

Madsen in combination with Hunter teach the limitations of instant Claims 11 - 13. With respect to claim 14, the modified Madsen discloses that the polymer solution has the ranges claimed hydrophilic polymer and additives but does not teach the recited % weight range of plasticizer.

Larsen teaches methods for making polymer articles such as catheters which are contacted with a solvent and a plasticizer (Abstract). Larsen teaches that when the plasticizer is combined with the swelling agent (solvent) the resulting solution preferably contains 50 – 90 % of the solvent and 1 - 50 % of the plasticizer (column 11, lines 14 – 27). The ranges taught by Larsen are essentially the same as those recited in the instant Claim.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to employ the recited ranges of plasticizer and solvent taught by Larsen in the method of Madsen and Hunter to prepare a coated catheter as such ranges have been taught Larsen to be suited to beneficially modify the flexibility or pliability of a catheter.

Response to Arguments

Applicant's arguments filed October 2, 2009 with respect to the rejection under 35 U.S.C 103(a) of Claims 11 – 21 as being unpatentable over Madsen in US 2002/0037943 in view of Hunter *et al.* in US 2004/0043052 have been fully considered but are moot in light of the Amendments to Claims 11 and 20 which require that the method include only a single irradiation step.

It is noted that in the response that Applicant has underlined the word 'may' (page 8) to, perhaps, draw attention to the fact that Madsen does not require a plasticizer, as required in step (ii) of the instantly claimed method. If this is, in fact, the basis for emphasizing the word 'may', it is noted that Madsen teaches a plasticizer

(paragraph [0070], irrespective of whether said plasticizer is required or optional. Finally, Applicant contends that Madsen does not teach or suggest the use of a single irradiation step which yields medical devices that have the excellent properties of medical devices prepared according to the claimed invention. In response, the Examiner notes that the properties of the medical device are not claimed and that Applicant has not provided evidence that the medical devices provided by Madsen in combination with Hunter, as cited in the 103(a) rejection of record are in any way distinct from those prepared by the instantly claimed method. Further, as noted in the 103(a) rejection above, Madsen teaches that medical devices prepared by the instantly claimed method provide catheters with the same 'excellent' properties of water retention and low coefficient of friction irrespective of whether the final sterilization step is carried out by irradiation or by autoclaving.

Conclusion

Claims 11 – 21 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, BRANDON FETTEROLF can be reached at (571)272-2919. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/Brandon J Fetterolf/

Primary Examiner, Art Unit 1642